

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

85552

ADMINISTRATIVE DOCUMENTS

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| NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT | | NDA NUMBER <div style="text-align: center; font-size: 1.2em;">85-552</div> |
| | | DATE APPROVAL LETTER ISSUED <div style="text-align: center; font-size: 1.2em;">SEP 15 1977</div> |
| TO: Press Relations Staff (HFI-40) | FROM: <input checked="" type="checkbox"/> Bureau of Drugs <input type="checkbox"/> Bureau of Veterinary Medicine | |
| ATTENTION Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above. | | |
| TYPE OF APPLICATION <input type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO NDA <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> SUPPLEMENT TO ANDA <input checked="" type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> TO ANDA | | CATEGORY <input checked="" type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY |
| TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG <div style="text-align: center; font-size: 1.1em;">Probenecid with Colchicine</div> | | |
| DOSAGE FORM <div style="text-align: center; font-size: 1.1em;">tablet</div> | | HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC |
| ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.) <div style="text-align: center; padding: 20px;"> Probenecid 500 mg. Colchicine 0.5 mg. </div> | | |
| NAME OF APPLICANT (Include City and State) <div style="text-align: center; padding: 10px;"> Chelsea Labs. Inwood, NY 11696 </div> | | |
| PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY <div style="text-align: center; font-size: 1.1em;">anti-gout</div> | | |
| COMPLETE FOR VETERINARY ONLY | | |
| ANIMAL SPECIES FOR WHICH APPROVED | | |
| COMPLETE FOR SUPPLEMENT ONLY | | |
| CHANGE APPROVED TO PROVIDE FOR | | |
| <div style="display: flex; justify-content: space-between;"> <div> NAME CChang <div style="font-size: 1.5em; margin-top: 10px;">/S/</div> </div> <div> FORM PREPARED BY <div style="font-size: 1.5em; margin-top: 10px;">/S/</div> </div> <div> DATE <div style="font-size: 1.2em; margin-top: 10px;">9-14-77</div> </div> </div> | | |
| <div style="display: flex; justify-content: space-between;"> <div> NAME JLMeyer <div style="font-size: 1.5em; margin-top: 10px;">JLM</div> </div> <div> FORM APPROVED BY <div style="font-size: 1.5em; margin-top: 10px;">JLM</div> </div> <div> DATE <div style="font-size: 1.2em; margin-top: 10px;">9/14/77</div> </div> </div> | | |